

STATE OF MICHIGAN
IN THE MICHIGAN SUPREME COURT

(On Appeal from the Michigan Court of Appeals
and the Circuit Court for the County of Eaton)

TERI WALTERS and KIM WALTERS

Sup. Ct. No. 154489

COA No. 319016

Trial Court No: 12-658-NH

Plaintiffs-Appellees,

v

DONALD S. FALIK d/b/a FALIK
FAMILY DENTISTRY; DONALD
S. FALIK, D.D.S.; ROBERT C. FALIK,
D.D.S. and JANE DOE, jointly and severally

Defendants-Appellants.

SULLIVAN, WARD, ASHER & PATTON, P.C.

**DEFENDANTS-APPELLANTS' SUPPLEMENTAL BRIEF IN SUPPORT OF
APPLICATION FOR LEAVE TO APPEAL**

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STATEMENT OF ISSUE

DID THE CIRCUIT COURT ACT WITHIN THE PROPER EXERCISE OF ITS DISCRETION IN STRIKING THE TESTIMONY OF PLAINTIFFS' MEDICAL CAUSATION EXPERT UNDER MRE 702 and MCL 600.2955 WHERE THE COURT CLOSELY SCRUTINIZED THE SUBSTANCE AND SCIENTIFIC BASIS OF THE EXPERT OPINION AND FOUND THE OPINION TO BE UNSUPPORTED BY ANY RELIABLE SCIENTIFIC PRINCIPLES OR METHODS - - INCLUDING THE COMPLETE ABSENCE OF AN ASSOCIATION BETWEEN PHOSPHORIC ACID AND WG?

The Circuit Court said: Yes

The Court of Appeals said: No

Plaintiffs-Appellees say: No

Defendants-Appellants say: Yes

ARGUMENT

THE CIRCUIT COURT ACTED WITHIN THE PROPER EXERCISE OF ITS DISCRETION IN STRIKING THE TESTIMONY OF PLAINTIFF'S MEDICAL CAUSATION EXPERT UNDER MCL 600.2955(1) AND MRE 702 WHERE THE COURT CLOSELY SCRUTINIZED THE SUBSTANCE AND SCIENTIFIC BASIS OF THE OPINION AND FOUND THE OPINION TO BE UNSUPPORTED BY ANY RELIABLE SCIENTIFIC PRINCIPLES OR METHODS.

This supplemental brief on behalf of Defendant-Appellant is filed pursuant to the following dictates of the Michigan Supreme Court, as set forth in its Order of May 10, 2017:

(1) whether the Court of Appeals erred in its interpretation of MCL 600.2955; and (2) whether the trial court erred in its application of those evidentiary standards or abused its discretion in granting the defendants' motions to exclude the plaintiff's experts' testimony and for summary disposition.

Order, 5-10-17, attached hereto as Exhibit A [emphasis added].

MRE 702 provides:

If the court determines that scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

MRE 702

MCL 600.2955 requires the court to determine whether the expert's opinion is reliable and will assist the trier of fact by examining the opinion and its basis, including the facts, technique, methodology, and reasoning relied on by the expert. *Elher v Misra*, 499 Mich 11; 878 NW 2d 790 (2016). The Court is to consider seven factors:

- (a) Whether the opinion and its basis have been subjected to scientific testing and replication.
- (b) Whether the opinion and its basis have been subjected to peer review publication.

(c) The existence and maintenance of generally accepted standards governing the application and interpretation of a methodology or technique and whether the opinion and its basis are consistent with those standards.

(d) The known or potential error rate of the opinion and its basis.

(e) The degree to which the opinion and its basis are generally accepted within the relevant expert community. As used in this subdivision, "relevant expert community" means individuals who are knowledgeable in the field of study and are gainfully employed applying that knowledge on the free market.

(f) Whether the basis for the opinion is reliable and whether experts in that field would rely on the same basis to reach the type of opinion being proffered.

(g) Whether the opinion or methodology is relied upon by experts outside of the context of litigation

MCL 600.2955(1)

A. The Michigan Supreme Court Nor The Legislature Have Yet To Recognize The Validity Of The Sir Bradford Hill Criteria Of Causation In Michigan, Especially Absent Scientific Studies Supporting The Association Between A Specific Agent And The Subject Disease

In Defendant's Application and supporting reply brief filed with the Supreme Court, Defendant demonstrated that it is improper for an epidemiologist to utilize in this state the Sir Bradford Hill criteria of causation as a substitute for the controlling statutory criteria of scientific reliability where: (1) the governing statute does not authorize the substitution and (2), in other jurisdictions, the Sir Bradford Hill criteria may not be used as an appropriate methodology by an epidemiologist to establish medical causation unless there is first a showing of the existence of independent data from controlled studies or other scientific recognition demonstrating an association between the agent and the medical condition at issue. This dictate is found in the 2011 Reference Guide on Epidemiology, which is published by the Federal Judiciary Center. This resource explains that the Bradford Hill factors cannot be

applied without first establishing a causal association. The 2011 Reference Guide on Epidemiology states.

In assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors . . . [o]nce this process is completed, researchers consider how guidelines for inferring causation from an association apply to the available evidence. **We emphasize that these [Bradford Hill] guidelines are employed only after a study finds an association to determine whether that association reflects a true causal relationship.**

2011 Reference Guide on Epidemiology at 598-99 (emphasis added, quoted in *Jones v Novartis Pharms Corp*, 2017 U.S. Dist LEXIS 10849, at * 51 (N.D. Ala, 1-26-17), attached hereto as Exhibit B) . A supplementary note further explains that "in a number of cases, experts attempted to use these guidelines to support the existence of causation in the absence of any epidemiologic studies finding an association . . . [t]here may be some logic to that effort, but it does not reflect accepted epidemiologic methodology." *Jones*, quoting 2011 Reference Guide on Epidemiology, p. 599 n. 141. Accord: *In re Lipitor*, 174 F. Supp 3d 911, 924-926 (DC S.C. 2015) and numerous cases cited therein.

B. The Trial Court Properly Exercised its Discretion to Bar Dr. Gershwin's Testimony

Supporting peer review publication and scientific studies are the first two criteria of reliability set forth in MCL 600.2955(1), *supra*. Other relevant statutory criteria include the existence of generally accepted standards governing the application of the expert's methodology and whether experts in the field would rely on the same basis to reach the type of opinion being proffered. As elaborated in Defendant's preexisting submissions to this Court, the trial court (and the Court of Appeals dissenting opinion) concluded that the absence of peer review publication and scientific studies supporting Dr. Gershwin's novel theory that etching

solution or phosphoric acid is associated with, causes, or in any way contributes to Wegener's Granulomatosis required the striking of his testimony as scientifically unreliable.

Contrary to the Court of Appeals' majority opinion and Plaintiffs' current arguments, the trial court's opinion was not based upon confusion regarding the contents of the articles used by Plaintiffs and its order was not an abuse of discretion because the absence of scientific data associating etching solution or phosphoric acid with WG renders Dr. Gershwin's reliance on the Bradford Hill criteria palpably erroneous as a matter of law. The Supreme Court should follow the position of the 2011 Reference Guide on Epidemiology in this regard; such a ruling would be clearly consistent with the criteria of MCL 600.2955(1).

C. There Remains No Known Cause of Wegener's Granulomatosis

Scientific authority such as the Cleveland Clinic Foundation, the Mayo Foundation for Medical Education and Research, and emedicine.medscape.com, Granulomatosis with Polyangiitis (Wegener Granulomatosis) Author: Christopher L Tracy, MD; Chief Editor: Herbert S Diamond, MD, Updated: Nov 21, 2016, continue to acknowledge no known cause of WG as of 2017. See: Exhibits C-E attached hereto). Consistently, Defendant has been unable to locate any reported authority which permits an expert witness to testify as to causation or otherwise permitted recovery in a lawsuit attributing causation regarding the development of WG. The testimony of Dr. Gershwin, attributing phosphoric acid as the proximate cause of Plaintiff's WG, especially absent supporting scientific data, is contrary to the knowledge of the relevant scientific community and scientifically unreliable as a matter of law. MCL 600.2955 (1)(e)-(g).

D. **The Court of Appeals Erroneously Applied a De Novo Standard of Review, As Now Admitted by Plaintiffs and Premised its Opinion Upon Speculative Analogy, Rather Than Reliable Proof**

As previously briefed, the Court of Appeals' majority opinion on remand cited to the "abuse of discretion" standard of review, but effectively engaged in its own de facto, *de novo* review of the trial court's analysis. Significantly, Plaintiffs themselves recognize this controlling fact, stating in their current brief:

"The COA rejected the Circuit's[sic] misapplication of MRE 702 and MCL 600.2955(1) **upon de novo review...**"(Appellees' Response to Application for Leave to Appeal, p. 2, emphasis added).

The Court of Appeals' majority's de facto employment of a *de novo* standard of review was palpably and reversibly erroneous. The text of the Court of Appeals' majority opinion does not explicitly demonstrate that the majority weighed whether the trial court's ruling fell "outside the range of reasonable and principled outcomes," *Elher v Misra*, 499 Mich 11; 878 NW 2d 790 (2016), or was "so palpably and grossly violative of fact and logic that it evidences perversity of will or the exercise of passion or bias rather than the exercise of discretion." *Maldonado v Ford Motor Co*, 476 Mich 372, 388, 719 NW2d 809 (2006). Rather, the Court of Appeals majority opinion reads as if the panel erroneously conducted its own de novo balancing of factors.

Again, This was reversible error.

Likewise, the Court of Appeals majority reversed the trial court's rejection of Dr Gershwin's reliance upon a speculative analogy to testing conducted of the relationship between silica and phosphates. The legal authority cited above and in Defendant's previous briefs requires scientific recognition of a **direct relationship** between a chemical agent and the disease in question. No analogies with analytical gaps are permitted.

Proper review of the Court of Appeals should have been limited to whether the trial court's rejection of the unsubstantiated analogies under the record evidence was **so palpably and grossly violative of fact and logic as to constitute an abuse of discretion**. Clearly, the **trial court's ruling was not an abuse of discretion**. The Court of Appeals majority's effective de novo analysis of the Court of Appeals majority which resulted in an improper perceived analogy between phosphates and phosphoric acid was reversible error.

CONCLUSION

The trial court's order was not an abuse of discretion. It should be reinstated by the Supreme Court.

Defendants-Appellants respectfully request this Honorable Court grant leave to appeal or peremptorily vacate the Court of Appeals opinion and affirm the order of the Eaton County Circuit Court striking Dr. Gershwin's testimony from consideration in this case.

Respectfully submitted,

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Dated: June 21, 2017
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